Food and Drug Administration, HHS

 $B\!\!=\!\!$ milligrams of ethylene glycol per milliliter of standard solution.

C=Peak height in millimeters of the diethylene glycol peak.

D=Milligrams of diethylene glycol per milliliter of standard solution.

PROCEDURE

Weigh approximately 4 grams of polyethylene glycol sample accurately into a 10-milliliter volumetric flask. Dilute to volume with water. Mix the solution thoroughly and inject a 2-microliter aliquot into the gas chromatograph. Measure the heights, in millimeters, of the ethylene glycol peak and of the diethylene glycol peak and record as E and F, respectively.

Percent ethylene $glycol=(E\times B)/(A\times sample$ weight in grams)

Percent diethylene glycol=(F×D)/(C×sample weight in grams)

- (c) *Uses.* It may be used, except in milk or preparations intended for addition to milk, as follows:
- (1) As a coating, binder, plasticizing agent, and/or lubricant in tablets used for food.
- (2) As an adjuvant to improve flavor and as a bodying agent in nonnutritive sweeteners identified in §180.37 of this chapter.
- (3) As an adjuvant in dispersing vitamin and/or mineral preparations.
- (4) As a coating on sodium nitrite to inhibit hygroscopic properties.
- (d) *Limitations*. (1) It is used in an amount not greater than that required to produce the intended physical or technical effect.
- (2) A tolerance of zero is established for residues of polyethylene glycol in milk

[42 FR 14491, Mar. 15, 1977, as amended at 49 FR 10105, Mar. 19, 1984]

§172.822 Sodium lauryl sulfate.

The food additive sodium lauryl sulfate may be safely used in food in accordance with the following conditions:

- (a) The additive meets the following specifications:
- $\dot{}$ (1) It is a mixture of sodium alkyl sulfates consisting chiefly of sodium lauryl sulfate [CH₂(CH₂)₁₀CH₂OSO₂Na].
- (2) It has a minimum content of 90 percent sodium alkyl sulfates.
 - (b) It is used or intended for use:
- (1) As an emulsifier in or with egg whites whereby the additive does not exceed the following limits:

Egg white solids, 1,000 parts per million. Frozen egg whites, 125 parts per million. Liquid egg whites, 125 parts per million.

- (2) As a whipping agent at a level not to exceed 0.5 percent by weight of gelatine used in the preparation of marshmallows.
 - (3) As a surfactant in:
- (i) Fumaric acid-acidulated dry beverage base whereby the additive does not exceed 25 parts per million of the finished beverage and such beverage base is not for use in a food for which a standard of identity established under section 401 of the Act precludes such use.
- (ii) Fumaric acid-acidulated fruit juice drinks whereby the additive does not exceed 25 parts per million of the finished fruit juice drink and it is not used in a fruit juice drink for which a standard of identity established under section 401 of the Act precludes such use.
- (4) As a wetting agent at a level not to exceed 10 parts per million in the partition of high and low melting fractions of crude vegetable oils and animal fats, provided that the partition step is followed by a conventional refining process that includes alkali neutralization and deodorization of the fats and oils.
- (c) To insure the safe use of the additive, the label of the food additive container shall bear, in addition to the other information required by the Act:
- (1) The name of the additive, sodium lauryl sulfate.
- (2) Adequate use directions to provide a final product that complies with the limitations prescribed in paragraph (b) of this section.

[42 FR 14491, Mar. 15, 1977, as amended at 43 FR 18668, May 2, 1978]

§ 172.824 Sodium mono- and dimethyl naphthalene sulfonates.

The food additive sodium mono- and dimethyl naphthalene sulfonates may be safely used in accordance with the following prescribed conditions:

- (a) The additive has a molecular weight range of 245–260.
- (b) The additive is used or intended for use:
- (1) In the crystallization of sodium carbonate in an amount not to exceed

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250 parts per million of the sodium carbonate. Such sodium carbonate is used or intended for use in potable water systems to reduce hardness and aid in sedimentation and coagulation by raising the pH for the efficient utilization of other coagulation materials.

- (2) As an anticaking agent in sodium nitrite at a level not in excess of 0.1 percent by weight thereof for authorized uses in cured fish and meat.
- (c) In addition to the general labeling requirements of the Act:
- (1) Sodium carbonate produced in accordance with paragraph (b)(1) of this section shall be labeled to show the presence of the additive and its label or labeling shall bear adequate directions for use.
- (2) Sodium nitrite produced in accordance with paragraph (b)(2) of this section shall bear the labeling required by §172.175 and a statement declaring the presence of sodium mono- and dimethyl naphthalene sulfonates.

 $[42\ FR\ 14491,\ Mar.\ 15,\ 1977,\ as\ amended\ at\ 63\ FR\ 7069,\ Feb.\ 12,\ 1998]$

§172.826 Sodium stearyl fumarate.

Sodium stearyl fumarate may be safely used in food in accordance with the following conditions:

- (a) It contains not less than 99 percent sodium stearyl fumarate calculated on the anhydrous basis, and not more than 0.25 percent sodium stearyl maleate.
- (b) The additive is used or intended for use:
- (1) As a dough conditioner in yeast-leavened bakery products in an amount not to exceed 0.5 percent by weight of the flour used.
- (2) As a conditioning agent in dehydrated potatoes in an amount not to exceed 1 percent by weight thereof.
- (3) As a stabilizing agent in nonyeast-leavened bakery products in an amount not to exceed 1 percent by weight of the flour used.
- (4) As a conditioning agent in processed cereals for cooking in an amount not to exceed 1 percent by weight of the dry cereal, except for foods for which standards of identity preclude such use.
- (5) As a conditioning agent in starchthickened or flour-thickened foods in

an amount not to exceed 0.2 percent by weight of the food.

§ 172.828 Acetylated monoglycerides.

The food additive acetylated monoglycerides may be safely used in or on food in accordance with the following prescribed conditions:

(a) The additive is manufactured by:

(1) The interesterification of edible fats with triacetin and in the presence of catalytic agents that are not food additives or are authorized by regulation, followed by a molecular distillation or by steam stripping; or

(2) The direct acetylation of edible monoglycerides with acetic anhydride without the use of catalyst or molecular distillation, and with the removal by vacuum distillation, if necessary, of the acetic acid, acetic anhydride, and triacetin.

(b) The food additive has a Reichert-Meissl value of 75–200 and an acid value of less than 6.

(c) The food additive is used at a level not in excess of the amount reasonably required to produce its in-

tended effect in food, or in food-processing, food-packing, or food-storage equipment.

[42 FR 14491, Mar. 15, 1977, as amended at 50 FR 3508, Jan. 25, 1985]

§172.829 Neotame.

- (a) Neotame is the chemical N-[N-(3,3-dimethylbutyl)-L- α -aspartyl]-L-phenylalanine-1-methyl ester (CAS Reg. No. 165450-17-9).
- (b) Neotame meets the following specifications when it is tested according to the methods described or referenced in the document entitled 'Specifications and Analytical Methods for Neotame' dated April 3, 2001, by the NutraSweet Co., 699 North Wheeling Rd., Mount Prospect, IL 60056. The Director of the Office of the Federal Register has approved the incorporation by reference of this material in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, 5100 Paint Branch Pkwy., College Park, MD 20740. Copies may be examined at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., rm.